

REMARKS

Claims 1-9, 11-15, 18-23, 26, 27, and 29-34 were pending in the application. Claims 1, 2, 19, 29, 31, and 32 are hereby amended. Claims 14, 15, and 18 are hereby cancelled. Claim 35 is newly added. No new subject matter has been added. After entry of this amendment, claims 1-9, 11-13, 19-23, 26, 27, and 29-35 will remain pending in this application.

Applicants believe that new claim 35 should be treated under 35 USC 112, sixth paragraph.

Claim Rejections Under 35 USC §112

Claims 1-9, 11-15, 18-23, 26-27 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the Examiner states that it is not clear where the flow regulator is placed relative to the inlet, NO scrubber, and buffer. While Applicants believe that the previously presented claim 1 was definite and that breadth does not equal indefiniteness (MPEP 2173.04), Applicants have amended claim 1 to limit the position of the flow regulator, in order to further prosecution. As amended, claim 1 now clearly states that the flow regulator is positioned between the inlet/outlet and the buffer chamber.

Also with respect to claim 1, the Examiner states that the claim is confusing for reciting only one inlet with the NO scrubber attached to it. The Examiner has requested clarification as to where the patient inhales No-scrubbed air and where the patient exhales No-scrubbed air. Applicants note that one of skill would understand that while the air inhaled is to be No-scrubbed, the air exhaled by the patient is not to be NO-scrubbed, as doing so would make measuring the patient's NO levels impossible. Amended claim 1 now recites an inlet/outlet that provides NO-scrubbed inhalation air to the patient and accepts exhalation air from the patient. An embodiment within the scope of the amended claim and employing an inlet/outlet is provided in Fig. 1. As depicted therein, NO scrubber 3 is connected to inlet/outlet 1. During use of the device of Fig. 1, a patient would inhale

air that has been scrubbed of NO (the air having passed through NO scrubber 3) via inlet/outlet 1 and then exhale into inlet/outlet 1. Applicants note, however, that reference to Fig. 1 is not intended in anyway to limit claim 1 to only such an embodiment. Applicants believe that this amendment clarifies the relationship between the NO scrubber and the inlet/outlet and that one of skill in the art would clearly understand the invention as claimed.

Applicants therefore respectfully assert that claim 1, as amended, meets the requirements of 35 U.S.C. 112, second paragraph.

The Examiner states that claim 6 is confusing because claim 1 does not claim separate devices for inhalation and exhalation. Applicants believe that the amendment of claim 1 to now state an inlet/outlet addresses the Examiner's concern. Applicants therefore respectfully assert that claim 6 meets the requirements of 35 U.S.C. 112, second paragraph.

The Examiner states that claim 15 is not clear. Applicants have cancelled claim 15 rendering this rejection moot.

The Examiner states that claim 19 is not clear regarding how the air sample is temporarily stored. Applicants assert that the Examiner is incorrectly equating breadth with indefiniteness. While claim 19 does not require storage in any particular manner, this absence of a required manner is clearly conveyed by the language of the claim, without ambiguity. Distinctness has two requirements, both of which are met by this element of claim 19:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

MPEP 2171. With respect to element (A), Applicants have set forth in claim 19 that they regard their invention as covering storing of exhaled air in a buffer chamber, without limitation as to the

manner of storage. With respect to element (B), the claims make clear that the metes and bounds of the claim, with respect to this step, are not limited by the particular method of storage. So, while the disclosure teaches an example of storage via closure of a 3-way valve 9 during initial exhalation (page 7, lines 8-17), Applicants do not regard their invention as being restricted to this particular embodiment and therefore clearly set forth that any method of storage in a buffer chamber would be sufficient to practice this step of the claimed method. For example, one of skill would clearly understand that alternative methods of storage (*e.g.*, a buffer chamber calculated to have a volume greater than the volume of exhaled air) would fall within the scope of the claim even though such an embodiment is not disclosed in the specification.

The Examiner also states that claim 19 is not clear in what is meant by “suitable” flow rate. Applicants have amended claim 19 to clarify that the sample is fed to the electrochemical NO sensor at a flow rate “lower than the exhalation flow rate.”

Applicants therefore respectfully assert that claim 19, as amended, meets the requirements of 35 U.S.C. 112, second paragraph.

The Examiner states that claim 29 is not clear in what is intended by the phrase “flow rate is higher than optimal for the NO sensor.” Applicants have amended claim 29 to strike the indicated phrase. Applicants therefore respectfully assert that claim 29, as amended, meets the requirements of 35 U.S.C. 112, second paragraph.

The Examiner states that claim 31 is not clear with respect to how the sample is temporarily stored in the buffer chamber. Applicants respectfully re-iterate the remarks made with respect to the similar rejection of claim 19.

The Examiner also states that claim 31 is not clear in what is intended by the phrase “flow rate is higher than optimal for the NO sensor.” Applicants have amended claim 31 to strike the indicated phrase.

Applicants therefore respectfully assert that claim 31, as amended, meets the requirements of 35 U.S.C. 112, second paragraph.

The Examiner states that claim 32-34 are not clear with respect to the physical position of each element. Claim 32, from which claims 33 and 34 depend, has been amended to match the inlet/outlet language of claim 1. Applicants respectfully assert that claim 32 clearly claims a NO scrubber that is connected to an inlet/outlet for providing inhalation air and receiving exhalation air and also connected to a separate ambient air inlet. Applicants respectfully assert that claims 32-34 meet all the requirements of 35 U.S.C. 112, second paragraph.

For the reasons stated above, Applicants respectfully request that all rejections under 35 U.S.C. 112, second paragraph be withdrawn.

Claim Rejections Under 35 USC §102

Claims 1, 4-9, 12-13, 19-22, 26-29 and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,222 ("Mault"). Applicants note that claim 28 has previously been cancelled and is no longer pending in the application.

Applicants respectfully submit that Mault fails to teach several key limitations of the present claims. With respect to device claim 1 and the claims that depend there from (claims 4-9, 12-13, 29-30, and 32-34) Mault particularly fails to disclose 1) a buffer chamber for storing a sample of the exhalation air, 2) an electrochemical sensor NO sensor, and 3) means for feeding the sample from the buffer chamber to the electrochemical NO sensor. With respect to method claims 19-27 and 31, Mault fails to disclose the related limitations of 1) storing a sample in a buffer chamber and 2) feeding the sample to an electrochemical NO sensor at a flow rate lower than the exhalation flow rate.

As an initial matter, Applicants note that Mault is directed to a portable calorimeter (*i.e.*, a device for measuring metabolic rate and related respiratory parameters). Mault at col. 1, lines 55-56, and col. 17, lines 20-27. Accordingly, the primary measurements of Mault are flow rate, volume of oxygen consumed (VO₂), and volume of carbon dioxide produced (VCO₂). Mault at col. 17, lines 20-50. So, while Mault does teach that other gases (including NO) may be measured, these measurements are not directly related to the primary calorimetric function. It is therefore not surprising that Mault provides little detail on how to perform these ancillary measurements, as discussed in more detail below.

Mault does not disclose a buffer chamber for storing a sample of the exhalation air

Mault fails to disclose a gas buffer chamber or the use of a gas buffer chamber. In the Office Action of May 15, 2009, the Examiner cites to Mault at column 11, lines 36-46 for the disclosure of the claimed buffer chamber. However, a careful review of the cited disclosure reveals that the buffers of Mault are memory or software buffers for storing data, rather than physical

buffers for storing a gas. The data stored within the memory buffers include transit times for pulses of sample and the differences between sequential measurements. Notably, the entire discussion of column 11 pertains to Figure 11 which depicts the electronic, rather than mechanical, systems of the Mault calorimeter.

Further, a review of the portions of Mault pertinent to exhalation gas handling reveal that the exhalation gas is not buffered in Mault. Rather, sample gases pass into and out of the device of Mault without reference to being stored in a buffer. Mault at col. 7, lines 9-40.

Applicants therefore respectfully assert that Mault fails to teach a buffer chamber or its use, as claimed.

Mault does not disclose an electrochemical NO sensor

While Mault does disclose an electrochemical sensor for measuring oxygen, Mault does not disclose an electrochemical sensor for measuring nitric oxide (NO) or its use. The Examiner cites to Mault at column 29, line 52 for the disclosure of an electrochemical sensor and to column 31, lines 49-53 for measurement of NO. However, the cited electrochemical sensor is an oxygen, rather than an NO, sensor. As discussed above, measurement of oxygen is primary to the calorimetric function of the Mault device. With respect to the measurement of NO disclosed by Mault, the cited paragraph starting at column 31, line 49 is the only mention in Mault of measuring NO, or any other gas that is not directly to the calorimetric function of the device. Mault provides no details on how to conduct NO measurements, and therefore does not enable NO measurement using any methods for doing so, beyond those known in the art. Certainly, Mault does not address any of the issues specific to the measurement of NO discussed in our specification or even in references previously cited by the Examiner. *See* Response dated August 19, 2008.

Applicants therefore respectfully assert that Mault fails to teach an electrochemical NO sensor or its use, as claimed.

Mault does not disclose means for feeding the sample from the buffer chamber to the electrochemical NO sensor at suitable flow rate

As discussed above, Mault does not disclose a buffer chamber or an electrochemical NO sensor. Accordingly, Mault is silent on means for feeding a sample from the buffer chamber to the electrochemical NO sensor, particularly at a rate suitable flow rate for the NO sensor that is lower than the exhalation flow rate. Because Mault is primarily concerned with calorimetry, Mault provides nothing more than a brief mention of measuring NO and does not address issues of flow rate with respect to electrochemical NO sensors.

Applicants therefore respectfully assert that Mault fails to teach means for feeding the sample from the buffer chamber to the electrochemical NO sensor at suitable flow rate or at a flow rate lower than the exhalation flow rate.

Applicants respectfully request that the rejection of claims 1, 4-9, 12-13, 19-22, 26-29 and 30-34 under 35 U.S.C. 102(e) be withdrawn.

Claim Rejections Under 35 USC §103

Claims 2-3, 23, and 30 over Mault

Claims 2-3, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault.

Applicants respectfully assert that Mault does not render the recited claims obvious for at least failing to teach or suggest all of the limitations of the claims, as discussed in the previous section. The Examiner has not articulated a rationale as to why it would be obvious to one of skill to modify Mault to include the missing elements of a buffer chamber, electrochemical NO sensor, or means for feeding sample from the buffer chamber to the NO sensor at a suitable flow rate.

Applicants respectfully request that the rejections of claims 2-3, 23, and 30 as being obvious over Mault be withdrawn.

Claims 14-15 and 18 over Mault in view of Holowko

Claims 14-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of U.S. Patent No. 6,039,251 ("Holowko").

Applicants note that claims 14, 15, and 18 have been cancelled. Applicants therefore respectfully request that the rejections of claims 14-15 and 18 as being obvious over Mault and Holowko be withdrawn.

Claim 11 over Mault in view of Birks

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of U.S. Patent No. 7,045,359 ("Birks").

Applicants respectfully assert that Birks does not address all of the deficiencies discussed above, with respect to Mault, so as to render the cited claims obvious. Applicants therefore respectfully request that the rejection of claim 11 as being obvious over Mault and Birks be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 514862000700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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